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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/610,313	07/05/2000	Susan Barnett	PP01631.101	4221

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EXAMINER	
ANGELL, JON E	

ART UNIT	PAPER NUMBER
1635	

MAIL DATE	DELIVERY MODE
12/31/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/610,313	BARNETT ET AL.	
	Examiner	Art Unit	
	J. Eric Angell	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 October 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-40 and 43-51* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *48-51* is/are allowed.

6)☒ Claim(s) *1-40 and 43-47* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All , b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10/11/2007 has been entered.

2. Applicant's arguments are addressed on a per section basis. The text of those sections of Title 35, U.S. Code not included in this Action can be found in a prior Office Action. Any rejections not reiterated in this action have been withdrawn as being obviated by the amendment of the claims and/or applicant's arguments.

Claims 1-40 and 43-51 are currently pending and are examined herein.

Information Disclosure Statement

3. The information disclosure statement (IDS) submitted on 10/11/2007 is acknowledged. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Priority

Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 120 as follows: The later-filed application must be an application for a patent for an invention which is also disclosed in the prior application (the

parent or original nonprovisional application or provisional application); the disclosure of the invention in the parent application and in the later-filed application must be sufficient to comply with the requirements of the first paragraph of 35 U.S.C. 112. See *Transco Products, Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir. 1994).

Instant claims 1-40 and 43-51 do not enjoy priority to co-pending US application 09/475,704 because application '704 does not provide written support for SEQ ID NO: 30-32. Figures 8-10 recited in instant claim 1 are not disclosed in '704. The Figures in '704 only go up to Figure 6 and are directed to a HIV Gag polypeptide.

Applicant's claim for domestic priority under 35 U.S.C. 119(e) is acknowledged. However, the provisional applications upon which priority is claimed fails to provide adequate support under 35 U.S.C. 112 for claims 1-40 and 43-51 of this application. Neither provisional application 60/114,495 nor 60/152,195 provide written description for SEQ ID NO: 30-32 in instant claims 1-40 and 43-51.

Thus, the instant application only enjoys priority to 7/5/00.

Applicant's arguments filed 10/11/2007 been fully considered but they are not persuasive.

Applicants contend that for the reasons of record the instant application should receive the benefit of priority to the indicated applications.

In response, for the reasons of record, Applicants' argument is not persuasive.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it

pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-40 and 43-47 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 1-40 and 43-47 as best understood, are readable on a genus of a polynucleotide sequence encoding an HIV Pol polypeptide that elicits a Pol-specific immune response, and further wherein the polynucleotide sequence encoding said Pol polypeptide comprises a nucleotide sequence having at least 90% sequence identity to the sequence presented in SEQ ID NO: 30, 31, or 32, wherein the genus of polynucleotide sequences is not claimed in a specific biochemical or molecular structure that could be envisioned by one skilled in the art at the time the invention was made are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The specification contemplates production of a genus of a polynucleotide sequence encoding a polypeptide including an immunogenic HIV Pol polypeptide, wherein the polynucleotide sequence encoding said Pol polypeptide comprises a nucleotide sequence having at least 90% sequence identity to the sequence presented in SEQ ID NO: 30, 31, or 32. The as-filed specification provides sufficient description of an immunogenic HIV Pol polypeptide set forth in SEQ ID NO: 30, 31, or 32. The specification does not define the term "an HIV Pol polypeptide that elicits a Pol-specific immune response." Importantly, the specification does not

disclose the structural elements of the Pol polypeptide which are critical for eliciting a "Pol-specific response" and which are not. As such, one of skill in the art would not be able to envisage which variants of SEQ ID NOS: 30-32 which meet the structural limitations of the claims (at least 90% identical to SEQ ID NO: 30, 31 or 32) would have the desired effect (ability to elicit a Pol-specific immune response and which variants would not elicit a Pol-specific immune response without performing additional experimentation. The specification defines an "immunological response" as humoral and/or cellular immune response (page 15) and the cellular immune response could include a response with CD4+ cells and/or CD8+ cells. The genus embraces an indefinite, but potentially very large number of polynucleotide sequences, considering every possible sequence that is at least 90% identical to SEQ ID NO: 30, 31 or 32. Note: considering that each of SEQ ID NOS 30-31 are at least 2457 nucleotides in length, there are more than 3,662,186,256 different sequences which are 90% to each of SEQ ID NOS: 30-32 (2457*.9=2211, 2457-2211= 246, since there are 4 different possibilities for each individual base difference (i.e., the other three bases and no base), there are 246^4 = 3,662,186,256 distinct sequences which are 90% identical to each of SEQ ID NO: 30-32). The specification does not disclose which nucleotides are considered essential for eliciting the "Pol-specific immune response". For example, the specification does not disclose what peptides encoded by SEQ ID NOs: 30-32 contains a CTL epitope.

The claims recite a structure and a function (polynucleotide encodes an HIV polypeptide that elicits a Pol-specific immune response) for the genus of polynucleotide sequences. However, the ability to elicit an immune response is a "function" common to almost all polypeptides. While, one skilled could envision a polynucleotide sequence that is at least 90%

identical to the claimed SEQ ID NOs., the skilled artisan would be unable to determine, based on the description in the specification, if the variant sequence could induce a "Pol-specific immune response" without performing additional experimentation. Thus, the specification does not disclose which polynucleotides with 90% sequence identity to the claimed SEQ ID NOs: 30-32 can induce a "Pol-specific immune response."

It is apparent that on the basis of applicants' disclosure, an adequate written description of the invention defined by the claims requires more than a mere statement that it is part of the invention and reference to potential methods and/or molecular structures of molecules that are essential for the genus of polynucleotide sequences as claimed; what is required is the knowledge in the prior art and/or a description as to the availability of a representative number of species of biochemical or molecular structures of polynucleotide sequences that must exhibit the disclosed biological functions as contemplated by the claims.

It is not sufficient for the specification to merely contemplate a genus of polynucleotide sequences (here, sequences which are at least 90% identical to SEQ ID NO: 30-32) and that have a desired effect (here, to encode an HIV Pol polypeptide that elicits a Pol-specific immune response), without disclosing the structural elements which are critical for the desired effect. The claimed invention as a whole is not adequately described if the claims require essential or critical elements, which are not adequately described in the specification and which is not conventional in the art as of applicants' effective filing date. Claiming a genus of polynucleotide sequences that must possess the biological properties as contemplated by applicants' disclosure without defining what means will do so is not in compliance with the written description requirement. Rather, it is an attempt to preempt the future before it has arrived. (See *Fiers v.*

Revel, 25 USPQ2d 1601 (CA FC 1993) and *Regents of the Univ. Calif. v. Eli Lilly & Co.*, 43 USPQ2d 1398 (CA FC, 1997)). Possession may be shown by actual reduction to practice, clear depiction of the invention in a detailed drawing, or by describing the invention with sufficient relevant identifying characteristics such that a person skilled in the art would recognize that the inventor had possession of the claimed invention. Pfaff v. Wells Electronics, Inc., 48 USPQ2d 1641, 1646 (1998). The skilled artisan cannot envision the detailed structure of the claimed genus of a polynucleotide sequences that encode an HIV Pol polypeptide that exhibits the ability to elicit a "Pol-specific immune response"; therefore, conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the structures and/or methods disclosed in the as-filed specification. Thus, in view of the reasons set forth above, one skilled in the art at the time the invention was made would not have recognized that applicant was in possession of the claimed invention as presently claimed.

Applicant's arguments filed 10/11/2007 have been fully considered but they are not persuasive for the reasons of record.

Applicants characterize the rejection as being based on:

> (a) the term "an HIV Pol polypeptide that elicits a Pol-specific immune response" is allegedly not defined and that the Pol polypeptides lacking non-immunogenic enzymatic functions are not described; and,
>
> (b) the previous evidence of record (PowerPoint slides presented by PTO, PTO Examples regarding written description, Declaratory evidence, and issuance of related patents) does not show that applicant had possession of the claimed genus. *Id.*

First, to clarify the basis of the rejection, the issue is whether or not the specification has sufficiently described the genus of polynucleotides that are encompassed by the claims. That is, the issue is whether or not the specification adequately describes the genus of polynucleotides

which include all polynucleotide sequences which are at least 90% identical to SEQ ID NO: 30, 31 or 32 and which encode an HIV Pol polypeptide which elicits a Pol-specific immune response. However, as indicated in the rejection, the specification does not indicate which structural elements of the claimed sequences are critical for conferring the required effect to the sequence. The previous evidence of record has been fully considered, but still one of skill in the art, at the time of filing could not have readily envisaged which sequences that are at least 90% identical to SEQ ID NO: 30, 31 or 32 would encode an HIV Pol polypeptide that elicits a Pol-specific immune response and which would not without performing additional experimentation. The fact the further experimentation would be required to identify which sequences that are at least 90% identical to SEQ ID NO: 30, 31 or 32 would encode an HIV Pol polypeptide that elicit a Pol-specific immune response indicates that at the time of filing the specification does not provide an adequate written description of the claimed genus of sequences.

The references that Applicants refer to in their arguments as supporting their position have been fully considered. However, the references do not demonstrate that, at the time of filing, the structural elements of SEQ ID NO: 30, 31 and 32 that are critical for encoding an HIV Pol polypeptide that elicits a Pol-specific immune response had been determined. As such, at the time of filing, one of skill in the art would not have been able to determine which sequences that meet the structural limitations of the claims also meet the functional requirement without performing additional experimentation.

Applicants argue that the genus of sequences encompassed by the claims is no where near as broad as is painted in the Final Office Action because the genus only includes sequences which meet the structural limitation and which also encode an HIV Pol polypeptide that elicits a

Pol-specific immune response—that is, if the sequence does not encode an HIV Pol polypeptide that elicits a Pol-specific immune response, it is not encompassed by the claims.

In response, it is acknowledged that the claimed genus only encompasses sequences which are BOTH 90% identical to SEQ ID NO: 30, 31 or 32 AND which encode an HIV Pol polypeptide that elicits a Pol-specific immune response. This implies that not all sequences which are 90% identical to SEQ ID NO: 30, 31 or 32 would encode an HIV Pol polypeptide that elicits a Pol-specific immune response. Therein lies the problem: if not all sequences which are 90% identical to SEQ ID NO: 30, 31 or 32 encode an HIV Pol polypeptide that elicits a Pol-specific immune response, which ones do and which ones do not? The specification and references of record do not provide enough information such that, at the time of filing, one of skill in the art could determine which sequences that are 90% identical to SEQ ID NO: 30, 31 or 32 would encode an HIV Pol polypeptide that elicits a Pol-specific immune response without performing additional experimentation. Therefore, the specification does not provide an adequate written description of the claimed genus of sequences.

Applicants argue that the as-filed specification teaches, in detail and with working examples, how to obtain additional polynucleotides with the recited structural and functional characteristics and satisfaction of the written description requirement does not necessitate that each and every member of the claimed genus be set forth, let alone "tested" in order to show possession. Applicants contend that the written description requirement does not necessitate a showing that the skilled artisan can predict a priori each and every nucleotide sequence falling within the scope of the claims. Even if it did, Applicants have met this inasmuch as the as-filed

specification contains unambiguous literal description of the structure of any member of the claimed genus by reference to its sequence similarity to a reference sequence.

In response, based on the disclosure of the specification, and in view of the prior art, a skilled artisan could not envision the detailed structure of the claimed genus of a polynucleotide sequences that encode an HIV Pol polypeptide elicits a Pol-specific immune response; therefore, conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the structures and/or methods disclosed in the as-filed specification. It is acknowledged that not every member of the genus must be identified and "tested". However, the specification must disclose the structure-function relationship in such detail that one of skill in the art could determine which sequences which meet the structural limitations would also have the required functional characteristics. Furthermore, a literal description of every sequence which is at least 90% identical to SEQ ID NO: 30, 31 or 32 provides no information as to which particular elements of the sequence are critical to the required function. Thus, it is not sufficient to be able determine every possible sequence that meets the structural limitations of the claims.

Therefore, Applicants arguments are not persuasive.

Double Patenting

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The

filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

Claims 1, 5-11, and 19-21 are rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1, 16-22, and 30-32 of U.S. Patent No. 7,211,659 (Application No. 10/190,435). Both sets of claims are directed to an expression cassette comprising a polynucleotide sequence encoding an HIV polypeptide and cells comprising the expression cassette. The polynucleotide sequence SEQ ID NO: 9 in the claims of '659 has at least 90% sequence identity to SEQ ID NO: 30-32 in the instant claims. (99.2% sequence identity with SEQ ID NO: 32). Furthermore, the limitations in instant claims 5-11 and 19-21 are the same as the limitations recited in claims 16-22 and 30-32 of the '659 patent.

Applicant requested that the provisional double patenting rejection be held in abeyance until indication of allowable claims in one of the applications (see 10/11/2007 communication). It is noted that Applicants did not take issue with the propriety of the rejection in the 10/11/2007 communication. Since the '435 Application has issued as the '659 patent, the rejection is no longer provisional.

Allowable Subject Matter

4. Claims 48-51 are allowed.

Conclusion

5. This is a Request for Continued Examination (RCE) Application. All claims are drawn to the same invention claimed in the application prior to filing the RCE and were finally rejected on the grounds and art of record in the previous Office action. Accordingly, **THIS ACTION IS**

MADE FINAL even though it is a first action in this case. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no, however, event will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to J. Eric Angell whose telephone number is 571-272-0756. The examiner can normally be reached on Monday-Thursday 8:00 a.m.-6:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Douglas Schultz can be reached on 571-272-0763. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/J. E. Angell/
Primary Examiner
Art Unit 1635